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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
10/526,430	02/13/2006	Markus Hecker	DEBE:052US/10501403	9671

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EXAMINER	
MONTANARI, DAVID A	

ART UNIT	PAPER NUMBER
1632	

MAIL DATE	DELIVERY MODE
04/16/2008	PAPER

Please find below and/or attached an Office communication concerning this application or proceeding.

The time period for reply, if any, is set in the attached communication.

Office Action Summary	Application No.	Applicant(s)	
	10/526,430	HECKER ET AL.	
	Examiner	Art Unit	
	DAVID MONTANARI	1632	

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE *3* MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

1)☒ Responsive to communication(s) filed on *15 January 2008*.

2a)☒ This action is **FINAL**. 2b)☐ This action is non-final.

3)☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

4)☒ Claim(s) *11-19* is/are pending in the application.

4a) Of the above claim(s) _____ is/are withdrawn from consideration.

5)☐ Claim(s) _____ is/are allowed.

6)☒ Claim(s) *11-19* is/are rejected.

7)☐ Claim(s) _____ is/are objected to.

8)☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

9)☐ The specification is objected to by the Examiner.

10)☐ The drawing(s) filed on _____ is/are: a)☐ accepted or b)☐ objected to by the Examiner.

Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).

Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).

11)☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

12)☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).

a)☐ All b)☐ Some * c)☐ None of:

1.☐ Certified copies of the priority documents have been received.

2.☐ Certified copies of the priority documents have been received in Application No. _____.

3.☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

1) ☐ Notice of References Cited (PTO-892)
2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)
3) ☐ Information Disclosure Statement(s) (PTO/SB/08) Paper No(s)/Mail Date _____.
4) ☐ Interview Summary (PTO-413) Paper No(s)/Mail Date. _____ .
5) ☐ Notice of Informal Patent Application
6) ☐ Other: _____.

DETAILED ACTION

1. Applicants arguments and amendments filed on 1/15/2008 have been entered.

2. Claims 1-10 are cancelled.

3. Claims 13, 14 and 19 are amended.

4. Claims 11-19 are examined in the instant application.

Claim Rejections - 35 USC § 103

The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

> (a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negatived by the manner in which the invention was made.

Claims 11-19 remain rejected under 35 U.S.C. 103(a) as being unpatentable over Chouini-Lalanne et al. (1998, Biochemical Pharmacology, Vol. 55, pgs. 441-446) and Ajmone-Cat et al. (2001, J. of Neuroscience Res., Vol. 66, pgs. 715-722) for reasons of record in the office action mailed on 10/17/2007.

Response to Arguments

Applicants argue in amendment filed on 1/15/2008 that regarding the term "pharmaceutical formulation", a claim limitation such as this must be considered on its merits. Applicants argue that In re Lerner teaches that an otherwise unpatentable compound would not be rendered patentable by addition of a carrier or diluent, how if the use of the carrier would not be obvious, the resulting composition would then be patentable. Applicants argue that Chouini-Lalanne discloses an in vitro test with DNA as a target for possible phototoxic actions of

NSAIDs, and that no in vivo administration of DNA-NSAID combinations is discussed or contemplated in their paper. Applicants continue that Ajmone-Cat merely discuss DNA-NSAIDs and thus cannot provide any motivation for adding a pharmaceutical carrier to the DNA-NSAID composition of the present invention.

Applicants continue to argue that neither Chouini-Lalane nor Ajmone-Cat disclose pH ranges of 6.2-7.0, but rather a pH of 7.4 for the DNA-NSAID composition. Applicants continue that it is well-established that some motivation must be provided by the examiner either by the prior art or the examiner. Applicants continue to argue that the examiner attempts to skirt this issue by claiming that optimization is not patentable, and that they submit that even optimization requires some motivation. Further Applicants argue that the case law cited by the examiner does not stand for any proposition that would obviate case law such as In re Vaeck. Applicants continue to assert no motivation exists in either Chouini-Lalane or Ajmone-Cat to drop the pH level to 6.2-7.0. Applicants continue that there is no mere "tweaking" of the formulation of Chouini-Lalane, but rather an increase of DNA uptake by 50% when the pH is dropped to 7.0 from 7.4.

These arguments are not persuasive. There is no mention of the term "in vivo" in any of the pending claims. This is important because Applicant is giving the phrase "pharmaceutical formulation" an "in vivo" weighted stance. Nothing about the phrase "pharmaceutical formulation" implies that it can only be for in vivo use, and pharmaceutical drugs are routinely tested in vitro. More importantly claim 1 states "A pharmaceutical formulation comprising", meaning that at least 1 or more components make up said formulation. In this case it is a nucleic acid and an NSAID, and that the composition of the DNA-NSAID exhibits a pH value from 6.2-

7.0 and further that the NSAID is present in a concentration range of 10 to 500 umol/l. Again, the term "pharmaceutical formulation" is given no patentable weight because the term pharmaceutical formulation provides no property to the DNA-NSAID composition discussed above that would distinguish it from the prior art. Simply put, the invention is a combination of DNA and NSAID's at a pH range and specific concentration, and for the purposes of this rejection the art of record teaches this. Applicants arguments that motivation is lacking in Chouini-Lalane and that the previous office action did not address the optimization of pH ranges are not correct. On page 4 of the previous non-final action, beginning at the last sentence, states that "However, even though applicant's modifications results in great improvement and utility over the prior art, it may still not be patentable if the modification was within the capabilities of one skilled in the art". Optimizing from pH 7.4 to the art accepted physiological neutral pH of 7.0 would be a predictable optimization given the in vivo intended use argued by the Applicant and easily within the capabilities of one skilled in the art. Further Applicants arguments concerning DNA uptake are also not persuasive since no functional language exists in any of the pending claims, and specifically language which recites DNA uptake amount. Nothing in the pending claims would indicate to the ordinary artisan that any special property or function exists in the claimed formulation that would distinguish it over the art of record. Again, the formulation comprises a nucleic acid and an NSAID at a physiologic pH range and concentration range for the NSAID, the art of record and the case law cited support that the ordinary artisan would have determined that the claimed formulation would have been obvious over the art of record. Thus for reasons above and of record the rejection is maintained.

No claims are allowed.

Conclusion

THIS ACTION IS MADE FINAL. Applicant is reminded of the extension of time policy as set forth in 37 CFR 1.136(a).

A shortened statutory period for reply to this final action is set to expire THREE MONTHS from the mailing date of this action. In the event a first reply is filed within TWO MONTHS of the mailing date of this final action and the advisory action is not mailed until after the end of the THREE-MONTH shortened statutory period, then the shortened statutory period will expire on the date the advisory action is mailed, and any extension fee pursuant to 37 CFR 1.136(a) will be calculated from the mailing date of the advisory action. In no event, however, will the statutory period for reply expire later than SIX MONTHS from the mailing date of this final action.

Any inquiry concerning this communication or earlier communications from the examiner should be directed to DAVID MONTANARI whose telephone number is (571)272-3108. The examiner can normally be reached on M-Tr 8-6.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Peter Paras can be reached on 1-571-272-4517. The fax phone number for the organization where this application or proceeding is assigned is 571-273-8300.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see http://pair-direct.uspto.gov. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free). If you would like assistance from a USPTO Customer Service Representative or access to the automated information system, call 800-786-9199 (IN USA OR CANADA) or 571-272-1000.

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/Peter Paras, Jr./
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